i·sens

Owner's Booklet

Soul™

Blood Glucose Monitoring System
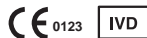
i·sens

i-SENS, Inc.
465-6 Wolgye4-dong, Nowon-gu
Seoul 139-845, Korea
www.i-sens.com

EC	REP

Medical Technology Promedt
Consulting GmbH,
Altenhofstrasse 80, D-66386
St. Ingbert, Germany

CE 0123 IVD

No-Coding System
Easy & Accurate Testing

CONTENTS

⋮ Important Information: Read this First!

To receive safe and optimum system benefits, please read the entire manual contents before using the system.
Please note the following instructions:

- Do not use the system for the diagnosis of diabetes without the guidance of a healthcare professional or for testing newborns.
- Use only fresh capillary whole blood samples for testing.
- Alternative site and fingertip test results may differ significantly due to rapid change in the glucose level post meal, insulin injection or exercise.

The following chart explains the symbols you'll find in the Soul User Manual, product packaging, and product inserts.

IVD	For *in vitro* diagnostic use
CE 0123	This product fulfills the requirements for Directive 98/79/EC on in vitro diagnostic medical devices
⚠	Cautions for safety and optimum product use
📖	Consult instruction for use
🏭	Manufacturer
EC REP	Authorized representative
⊘	Do not reuse
LOT	Batch code
☒	Do not discard this product with other household-type waste
SN	Serial number

⧗ Use by

Temperature limitations (+8℃ to +30℃)

Important Information

- The Soul blood glucose monitoring system is intended for self-testing outside the body (*in vitro* diagnostic use).

- The glucose in the blood sample mixes with special chemicals on the test strip where to produce a small electrical current. The Soul meter detects this electrical current and measures the amount of glucose in the blood sample.

- The Soul blood glucose meter is designed to minimize code related errors in monitoring by using the no-coding function.

- The Soul blood glucose meter should be used only with the Soul strip.

- The average hematocrit range is between 30 and 50%. However, people with severe anemia, pregnant women and newborns may have higher hematocrit and this can affect the test results.

- Very high (60% or more) or very low (20% or less) hematocrit can lead to incorrect test results.

- A glucose value of less than 70 mg/dL (3.9 mmol/L) may indicate hypoglycemia and a value of more than 240 mg/dL (13.3 mmol/L) may indicate hyperglycemia.

If you need assistance, please contact your authorized i-SENS sales representative or visit www.i-sens.com for more information.

Specifications

Product specifications	
Reported result range	20 ~ 600 mg/dL (1.1 ~ 33.3 mmol/L)
Sample size	Minimum 0.5$\mu\ell$
Test time	5 seconds
Sample type	Fresh capillary whole blood
Calibration	Plasma-equivalent
Assay method	Electrochemical
Battery life	1,000 tests
Power	Two 3.0 V lithium batteries (disposable, type CR2032)
Memory	250 test results
Size	90.3 X 49.2 X 14.5 (mm)
Weight	50.5 g (with battery)

Operating ranges	
Temperature	10 ~ 40°C (50 ~ 104°F)
Relative humidity	10 ~ 90%
Hematocrit	20 ~ 60%

Soul Blood Glucose Monitoring System

Components

① Soul Blood Glucose Meter
② Lancing Device
③ Lancet (10)
④ Owner's Booklet
⑤ Quick Reference Guide
⑥ Logbook
⑦ Carrying Case
⑧ Soul Blood Glucose Test Strip (10)
⑨ Battery (2)

- Check all the components after opening the Soul blood glucose monitoring system package.
- Please contact your authorized i-SENS sales representative if any component is missing or damaged.
- The PC care cable for data transmission can be ordered separately. Please contact your authorized i-SENS sales representative or visit www.i-sens.com.

Soul Blood Glucose Test Strip

The Soul blood glucose monitoring system measures blood glucose quickly and accurately. It automatically absorbs the small blood sample applied to the narrow edge of the strip.

Insert

Contact bars
Gently push the test strip, with its contact bars facing up, into the test strip port of meter

Confirmation window
Check here to see whether sufficient blood sample has been applied

Edge to apply blood sample
Apply blood sample here for testing
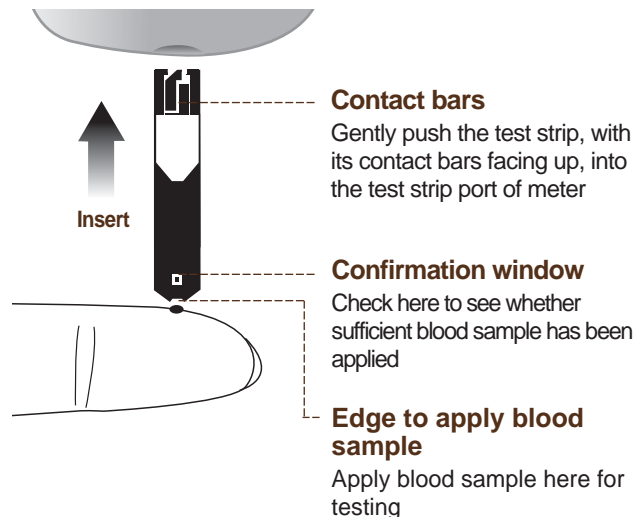
Soul Blood Glucose Test Strip

Warning!

- The Soul test strip should be used only with fresh capillary whole blood samples.
- Do not reuse test strips.
- Do not use test strips past the expiration or discard date.
- Check the expiration date printed on the vial. When you first open a test strip vial, you must record the discard date (date opened plus 6 months) in the space provided on the label.
- Store test strips in a cool and dry place at a temperature of 8 ~ 30˚C (46 ~ 86˚F).
- Keep away test strips from direct sunlight or heat and do not refrigerate or freeze.
- Store test strips only in their original vial.
- Close the vial tightly after removing a test strip for testing and use the strip immediately.
- Handle test strips only with clean and dry hands.
- Do not bend, cut, or alter test strips in any way.
- For detailed storage and usage information, refer to the Soul test strip package insert.

Caution	Keep the meter and testing supplies away from young children.

Soul Blood Glucose Meter

Transmission Port
Used to transfer data from the meter to a computer with a PC care cable

Display
Shows results, messages

M Button
Turns the meter on/off and confirms menu selections

C Button
Selects or changes information

Test Strip Port
Insert test strip here

The PC care cable for data transmission to PC can be ordered separately. Please contact your authorized i-SENS sales representative or visit www.i-sens.com.

⦿ Soul Blood Glucose Meter Display

mem
appears when test results stored in the memory are displayed

alarm
appears when the time alarm has been set

Battery icon
indicates meter battery is running low and needs to be replaced

Post-meal test flag
appears during post-meal testing and when post-meal test results are displayed

Sound icon
appears only when the sound is set to OFF

check
appears when test results have not been saved
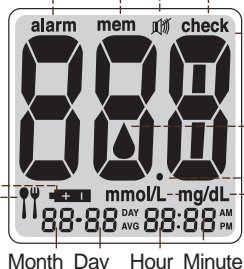
Test results
test results displaying panel

Blood insertion icon
indicates meter is ready for the application of a drop of blood or control solution

Decimal point
appears when the blood glucose measuring unit is set to mmol/L

mmol/L, mg/dL
unit for measuring blood glucose

alarm   mem   〚〛 check

mmol/L   mg/dL
88·88 DAY AVG 88:88 AM PM

Month   Day   Hour   Minute

⦿ Setting up Your System

Press and hold the M button for 3 seconds to switch on the meter. After all settings are finished, press and hold the M button for 3 seconds to turn off the meter.
Press C button to reach the accurate value. Press and hold C button to scroll faster.

Adjusting the Date, Time and Unit

Step 1
Entering the SET Mode
Press and hold the M button for 3 seconds to switch on the meter.
After all the segments flash across the screen, the 'SET' character icon will be displayed on the screen. Press the M button again to enter the year setting mode.

Step 2
Setting the Year
The number that appears on the screen after the meter is turned on indicates the year of manufacture. Press and release C button to adjust until the correct year appears.
Press and hold C button to scroll through the numbers quickly. After setting the year, press the M button to confirm your selection and enter the month setting mode.

SET

10
mg/dL
1·01   12:00 PM
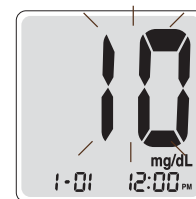
Setting up Your System

Step 3
Setting the Month

A number indicating the month will be blinking on the left corner of the screen. Press C button until the correct month appears. Press the M button to confirm your selection and enter the date setting mode.

Step 4
Setting the Date

Press C button until the screen displays the correct date. Press the M button to confirm the date and enter the time setting mode.

Step 5
Setting the Time

The meter can be set in the AM/PM 12-hour or the 24-hour clock format. Press C button to select a format. The AM • PM icon is not displayed in the 24-hour format. After selecting the format press the M button to enter the hour setting mode.
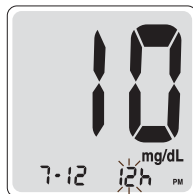
Step 6
Setting the Hour

Press C button until the correct hour appears.

After the hour is set, press the M button to enter the minute setting mode.

Step 7
Setting the Minute

Press C button until the correct minute appears. After setting the minute, press the M button to enter the unit setting mode

Step 8
Setting the Measurement Unit

The meter is set to mg/dL. Press C button to change to mmol/L or to return to mg/dL. Press the M button to confirm your selection and to enter the sound setting mode. However, in some countries, the meter may have been set to the unit generally used in the country (mg/dL or mmol/L). In this case, the unit can not be changed and the unit change setting step will be excluded.

| Caution | The unit setting on the meter may be fixed for your meter, so that you will not be able to change the setting. |

Setting up Your System

### Setting the Sound On/OFF

Step 9

On pressing C Button, the screen will display the On or OFF.
Press the M button to confirm the selection.

The meter will beep in the following instances, if set to On.
- When the test strip is inserted in the meter
- When the blood sample is absorbed into the test strip and the test starts
- When the test result is displayed
- When it is time for a preset blood glucose test

If the sound is set to OFF, none of the sound functions will work.

| Note | Only when the sound is set to OFF, 🔊 icon appears on the display. |
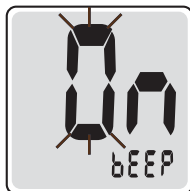
Setting the 'Test Result Reset'
**(Deleting all the saved test results)**

Step 10

In this mode all the test results stored in the meter can be deleted.
Please note that if you select YES, all the stored test results will be deleted and can not be restored.
After the beeper mode is set, press the M button to enter the 'Test Result Reset' mode. The 'dEL' character will blink on the screen. Press C button to alternate between 'YES' or 'no'.
To delete all the stored test results press the M button while the screen displays 'YES'. Then, all the test results stored in the meter will be deleted and the screen will be similar to the picture on the right.
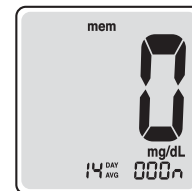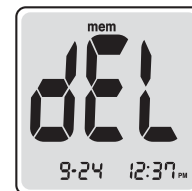
If you do not want to delete the results press the M button while the screen displays 'no'. Then, the screen will return to step 1. See page 9.

| Note | At any stage, if the M button is pressed for 3 seconds, the Time, Date and Unit setting mode will finish and the meter will be turned off. Press and hold C button to scroll through numbers quickly. |

Using the Lancing Device

You will need a lancing device in order to collect a blood sample. You may use the lancing device contained in the Soul Blood Glucose Monitoring System or any other medically approved lancing device.

Ejection System

Adjustable Tip Lancet Holder

Sliding Barrel

Release Button
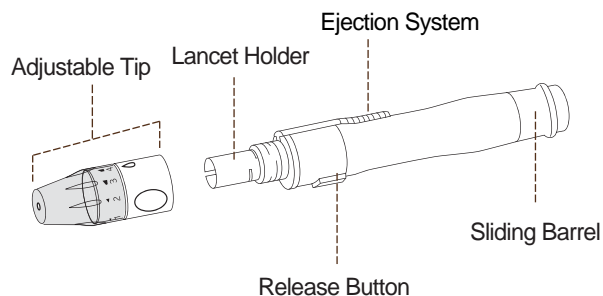
Caution	To avoid infection when drawing a sample, use a lancet only one time, and: • Do not use a lancet that has been used by others. • Always use a new sterile lancet. • Keep the lancing device clean.

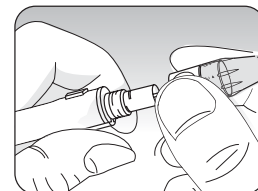## Preparing the Lancing Device for Blood Sample Retrieval

Step 1
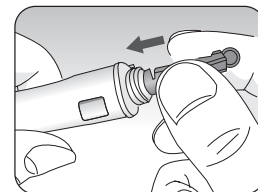Wash hands and fingertip sample site with soap and warm water. Rinse and dry thoroughly.
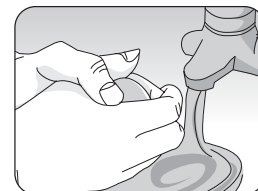
Step 2
Unscrew lancing device tip.

Step 3
Firmly insert new lancet into carrier. Hold lancet firmly. Gently twist to pull off protective disk. Save disk to recap lancet after use. Replace lancing device tip.
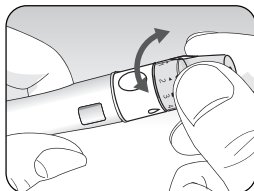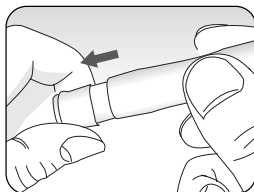
⚬ Using the Lancing Device

Step 4

Select a desired depth of one-to-five (1-5) on lance's adjustable tip. Rotate ring to align desired number with arrow.
A beginning setting of three (3) is recommended.

Step 5

To cock the lancing device, hold the tip in one hand. Pull the sliding barrel on with the other hand. The lancing device is cocked when you feel a click.

Preparing the Meter and Test Strip

Step 6

Insert a test strip with the contact bars facing upwards into the meter port. Push the strip in gently until the meter beeps. Be careful not to bend the test strip. The ⬆ symbol will appear on the screen.
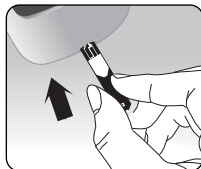
[Flagging Post-meal Test Results]

The Soul meter allows you to flag a result of an post-meal test with (⇈) icon. The post-meal test flag (⇈) can be attached just before applying the blood sample. Once you attach the post-meal flag (⇈) to the test results, it cannot be deleted.

Step 7

If you want to attach a post-meal flag (⇈) to a test result, press and hold C button for 3 seconds after inserting the test strip. The post-meal flag (⇈) and the ⬆ symbol will appear on the screen. The test result will also be displayed with the post-meal flag (⇈).
If you do not want to save the result a post-meal test, move on to the step 8 after the step 6.
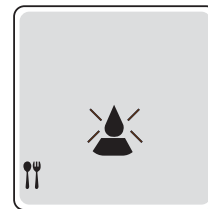
Applying Blood Sample

Step 8

Obtain a blood sample using the lancing device. Place the device against the pad of the finger. The best puncture sites are on the middle or ring fingers. Press the release button. Remove the device from the finger. Wait a few seconds for a blood drop to form. A minimum volume of 0.5 microliter is needed to fill the confirmation window. (actual size of $0.5 \mu \ell$: ●)
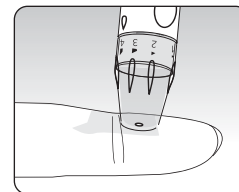
Step 9

After the ♠ symbol appears on the screen, apply the blood sample to the narrow end of the test strip till the meter beeps. If the confirmation window is not filled before the meter finishes counting down then discard the test strip and insert a new one.

If confirmation window is not filled in time because of abnormal viscosity or insufficient volume, Er4 message will appear.
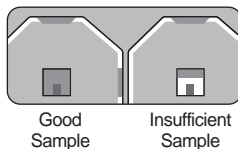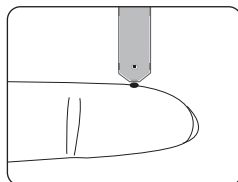
Good Sample   Insufficient Sample

Note	The meter may switch off if the blood sample is not applied within 2 minutes of the ♠ icon appearing on the screen. If the meter turns off, remove the strip and reinsert.

Step 10

The test result will appear after the meter counts down from 5 to 1. The result will be automatically stored in the meter's memory. If the test strip is removed after the test result is displayed, the meter will automatically switch off after 3 seconds.
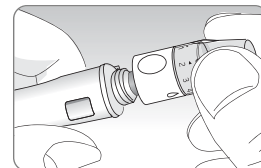
Discard used test strips safely in disposable containers.

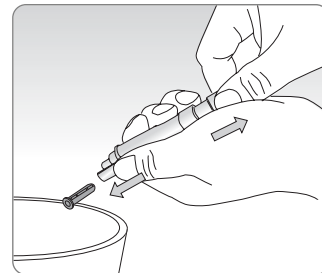## Discarding Used Lancets

Step 1

Unscrew general lancing device tip.

Step 2

Place protective cover on lancet. Pull out the sliding barrel and push the lancet ejector forward with the thumb to dispose of the used lancet in a proper biohazard container.


Caution	The lancet is for single use only. Never share or reuse a lancet. Always dispose of lancets properly.

Alternative Site Testing

What is AST (Alternative Site Testing)?

Usually, when someone tests their glucose, they take the blood sample from the tip of the finger. However, since there are many nerve endings distributed there, it is quite painful. When doing a glucose test, using different parts of the body such as the arms, palms, thighs, and calves can reduce the pain during testing. This method of testing with different parts of the body is called Alternative Site Testing. While AST may reduce the pain during testing, it may not be simple for everyone and the following precautions should be observed during testing.

Alternative Site for Testing
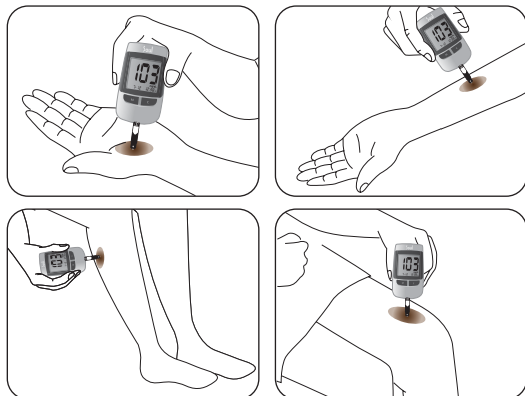
Please understand the following things before testing outside of the fingertip (arms, thighs, calves).
The capillary blood of the fingertip shows the change in glucose more rapidly than AST. Therefore, the test results from the fingertip test and AST may differ. This is because things such as lifestyle and ingested food have an effect on glucose levels.

Acceptable situations for AST

• Fasting period
• Before a meal
• Before sleeping

Situations requiring fingertip test

• When the glucose levels are rapidly increasing during the two hours after a meal or exercise
• When sick or when glucose levels seem quite lower than test value
• When hypoglycemia is not well recognized
• When insulin has the biggest effect
• 2 hours after an insulin injection
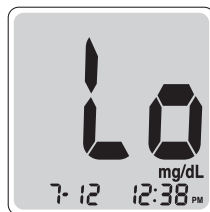
Hi and Lo Messages

Hi Message

The meter displays results between 20 ~ 600 mg/dL (1.1 ~ 33.3 mmol/L). The Hi icon appears when the blood glucose level is more than 600 mg/dL (33.3 mmol/L) and indicates hyperglycemia.
If the Hi icon is displayed again on retesting, please contact your healthcare professional immediately.

HI

mg/dL

7- 12   12:38 PM

Lo Message

The Lo icon appears when the result is less than 20 mg/dL (1.1 mmol/L) and indicates hypoglycemia.
If the Lo icon is displayed again on retesting, please contact your healthcare professional immediately.

Lo

mg/dL

7- 12   12:38 PM

Note	Please contact your authorized i-SENS sales representative, if such messages are displayed even though you do not have hyperglycemia or hypoglycemia.

Target Blood Glucose Ranges

Reminders

Time of day	Your target ranges from your healthcare expert
Before breakfast	
Before lunch or dinner	
1 hour after meals	
2 hours after meals	
Between 2 a.m. and 4 a.m.	

Source : *Diagnosis of Diabetes*, NIH Publication
No. 05-4642, January 2005

⁚ Meter Memory

The Soul meter can save up to 250 glucose test results with time and date. If the memory is full, the oldest test result will be deleted and the latest test result will be stored.
The Soul meter calculates and displays the averages of total test results, pre-meal test results, and post-meal test (🍴) results from the last 14 days.

Viewing Test Results Stored in the Meter's Memory

Step 1

Press the C button or M button to turn the meter on. The current date and time will be displayed on the bottom of the screen for 2 seconds, followed by the average value and the number of the test results saved within the last 14 days.
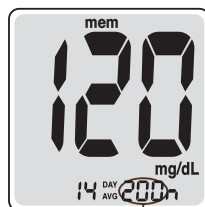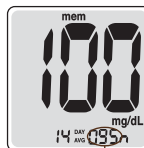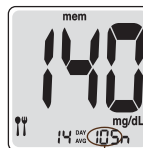

The number of total tests

Step 2

Press C button to view the average value and the number of tests performed before eating a meal for the last 14 days.
On pressing C button again, the average value and the number of tests performed post meals for the same period will appear on the screen.

The number of pre-meal tests

The number of post-meal tests

Step 3

Each time you press the C button, you will see previous test results, dates and times displayed in chronological order.
After checking the stored test results, press the M button to turn off the meter.
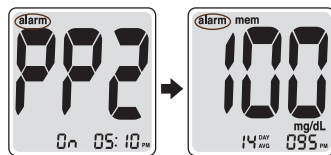
⚬ Setting the Alarm Function

The Soul meter has a post-meal alarm (PP2 alarm).
The PP2 alarm goes off 2 hours after setting the alarm. The alarms ring for 15 seconds and can be silenced by pressing C button or the M button or by inserting a test strip.

### Setting the post-meal alarm (PP2 alarm)

Step 1   Setting the PP2 alarm On

Without inserting a test strip, press and hold C button for 3 seconds to set the post-meal alarm. The 'PP2' character, the alarm icon and then the 'On' character will be displayed. The screen will then automatically change to the memory check mode. At this time, the alarm icon, indicating that the PP2 alarm has been set, will be displayed on the screen. To exit the memory check mode and turn off the meter, push the M button.

Step 2   Setting the PP2 alarm OFF

To turn off the PP2 alarm, press and hold C button for 3 seconds. The 'PP2'character, the alarm icon and then the 'OFF' character will appear on the screen. Then the screen will change automatically to the memory check mode without the alarm icon being displayed. The alarm will not sound if you have turned the sound off.
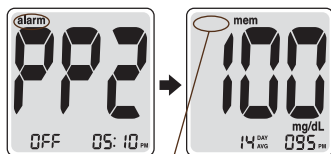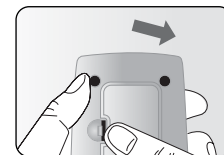
⚬ Replacing the Batteries

The Soul meter comes with two 3.0 V lithium batteries.
Around 50 tests can still be carried out after the ▬▬ icon appears on the display for the first time, but the battery should be replaced as soon as possible. The test results will not be saved if the ▬▬ icon appears.

Step 1

Make sure the meter is turned off. Push the cover in the direction of the arrow to open the battery compartment.

Step 2

Pull the plastic tape up and remove the old batteries.
Insert two new batteries with the + side facing up as shown in the figure.
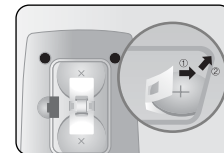
Step 3

Place the cover over the battery compartment. Push down until you hear the tab click into place.

Note	Replacing batteries has no effect on the test results previously saved. After replacing batteries, you may need to reset your meter setting.

Checking the System

You may check your meter and test strips using the Soul Control Solution.
The Soul Control Solution contains a known amount of glucose and is used to check that the meter and the test strips are working properly. The test strip vials have Soul Control Solution ranges printed on their labels. Compare the result displayed on the meter to the Soul Control Solution range printed on the test strip vial.
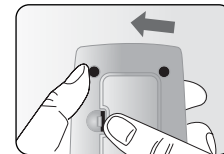Before using a new meter or a new vial of test strips, conduct a control solution test following the procedure on page 27.

Notes:

• Use only the Soul Control Solution.
• Check the expiration dates printed on the vial. When you first open a control solution vial, record the discard date (date opened plus three months) in the space provided on the label.
• Make sure your meter, test strips, and control solution are at room temperature before testing. Control Solution tests must be done at room temperature (20 ~ 25˚C, 68 ~ 77˚F).
• Before using the control solution, shake the vial, discard the first few drops and wipe the tip clean.
• Close the control solution vial tightly and store at a temperature of 8 ~ 30˚C (46 ~ 86˚F).

Do a Control Solution test:

• When using the meter for the first time
• Whenever you open a new vial of test strips
• If the meter or test strips do not function properly
• If your symptoms are inconsistent with the blood glucose test results and you feel that the meter or test strips are not working properly
• If you drop or damage the meter

Note	If all the results you get on testing three times continuously are within the range printed on the test strip, the meter and test strips are working properly and you may use them for your blood glucose test.

Control Solution Testing

Step 1

Insert a test strip with the contact bars facing upwards into the meter port. Push the strip in gently until the meter beeps. Be careful not to bend the test strip. The ♠ symbol will appear on the screen.
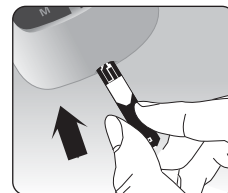
Step 2

Shake the Soul Control Solution vial before each test. Remove the cap and squeeze the vial to discard the first drop. Then wipe the tip with a clean tissue or cloth.
After the ♠ symbol appears on the display, apply the solution to the narrow edge of the test strip until the meter beeps. Make sure the confirmation window fills completely.
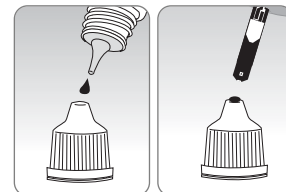
Note	The meter may switch off, if the blood sample is not applied within 2 minutes of the ♠ icon appearing on the screen. If the meter turns off, remove the strip, reinsert, and start from step 1.

⦂ Checking the System

Step 3

A test result will appear after the meter counts down from 5 to 1.
After your control solution result appears on the display, press C button for 3 seconds till the 'check' icon appears on the display. When the 'check' icon is displayed, the result is not stored in the meter's memory and is not included in the 14-day averages.

Step 4

Compare the result displayed on the meter to the range printed on the test strip vial.
The result should fall within that range.
Used strips should be discarded safely in disposable containers.

Control Solution Range
Centrol A : 100-148mg/dL
Centrol B : 191-1286mg/dL

LOT
Discard Date :

Comparing the Control Solution Test Results

Repeat the control test if the test result falls outside the range printed on label of the test strip vial. Out of range results may occur due to the following factors:

- When the control solution vial was not shaken well,
- When the control solution is past its expiration date or is contaminated,
- When the meter, the strip or the control solution were exposed to high or low temperatures,
- When the first few drops of the control solution were not discarded or the tip of the vial was not wiped clean,
- When the test strip is past its expiration date,
- When the meter is not functioning properly.

Caution	• If the results you get are not within this range, the meter and test strip may not work properly. Then, stop using the meter and contact the nearest i-SENS representative. • The range printed on the test strip vial is for the Soul Control Solution only. It does not have any connection to your blood glucose level.

Note	The Soul Control Solution can be purchased separately. Please contact your authorized i-SENS sales representative.

Caring for Your System

Use a soft cloth or tissue to wipe the meter exterior. If necessary, the soft cloth or tissue might be dipped in a small amount of alcohol.
Do not use organic solvents such as benzene, or acetone, or household and industrial cleaners that may cause irreparable damage to the meter.
Store all the meter components in the portable case to prevent loss.

Caution:
- Do not expose the meter to direct sunlight or heat for an extended period of time.
- Prevent the entry of dirt, dust, blood, or water at the meter's test strip port.
- Do not drop the meter or submit it to strong shocks.
- Do not try to fix or alter the meter in any way.
- Keep the meter away from strong electromagnetic fields such as cell phones and microwave ovens.
- Soul meter should be used only with Soul strips.
- Store the meter at a temperature between 10 ~ 40˚C.

Understanding Error and Other Messages

Message	What It Means	What To Do
Er1	A used test strip was inserted.	Repeat the test with a new test strip.
Er2	The blood or control solution sample was applied before the ▲ icon appeared.	Repeat the test with a new test strip and wait until the ▲ icon appears before applying the blood sample.
Er3	The temperature during the test was above or below the operating range.	Move to an area where the temperature is within the operating range (10 ~ 40˚C/ 50 ~ 104˚F) and repeat the test after 30 minutes.

○ Understanding Error and Other Messages

Message	What It Means	What To Do
Er4	The blood sample has abnormally high viscosity or insufficient volume.	Repeat the test after inserting a new test strip.
Er5	A test strip was not inserted properly.	Try to insert a test strip properly.
Er6	There is a problem with the meter.	Do not use the meter. Contact your authorized i-SENS sales representative.

Caution	If the error messages persist, contact your authorized i-SENS sales representative.

○ General Troubleshooting

Problem Message	What Troubleshooting Means
The display is blank even after inserting a test strip.	• Check whether the test strip is inserted with the contact bars facing up. Check if the strip has been inserted completely till the end. • Check whether the batteries are inserted with the '+' side facing up. • Replace the batteries.
The test does not start even after applying the blood sample on the strip.	• Check if the confirmation window is filled adequately. • Repeat the test after inserting a new test strip.
The test result doesn't match your expectation.	• Repeat the test after inserting a new test strip. • Check the validity period of the test strip. • Check if the strip has passed the discard date (date of opening the test strip vial plus 6 months). • Check the meter.

NOTE	If the problem is not resolved, please contact your authorized i-SENS sales representative.

Performance Characteristics

The performance of Soul Blood Glucose Test Strips has been evaluated in laboratory and in clinical tests.

Accuracy : The accuracy of the Soul BGM System (GM505K) was assessed by comparing blood glucose results obtained by patients with those obtained using a YSI Model 2300 Glucose Analyzer, a laboratory instrument. The following results were obtained by 122 diabetic patients at clinic centers.

Slope	1.02
Y-intercept	-7.39 mg/dL
Correlation coefficient (r)	0.992
Number of sample	122
Range tested	40 ~ 577 mg/dL

Accuracy results for glucose concentration<75 mg/dL (4.2 mmol/L)

Within ± 5 mg/dL (Within ± 0.28 mmol/L)	Within ± 10 mg/dL (Within ± 0.56 mmol/L)	Within ± 15 mg/dL (Within ± 0.83 mmol/L)
11/11 (100%)	11/11 (100%)	11/11 (100%)

Accuracy results for glucose concentration≧75 mg/dL (4.2 mmol/L)

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
47/111 (42%)	89/111 (80%)	109/111 (98%)	111/111 (100%)

Precision : Precision studies were performed in a laboratory using the Soul BGM System.

Within Run Precision		
Blood average	41.4 mg/dL (2.3 mmol/L)	SD = 1.8 mg/dL (0.1 mmol/L)
Blood average	79.6 mg/dL (4.4 mmol/L)	CV = 3.5%
Blood average	129.8 mg/dL (7.2 mmol/L)	CV = 2.6%
Blood average	201.9 mg/dL (11.2 mmol/L)	CV = 3.1%
Blood average	349.6 mg/dL (19.4 mmol/L)	CV = 2.7%

Total Precision		
Control average	36.2 mg/dL (2.0 mmol/L)	SD = 1.3 mg/dL (0.07 mmol/L)
Control average	117.0 mg/dL (6.5 mmol/L)	CV = 2.3%
Control average	321.8 mg/dL (17.9 mmol/L)	CV = 2.4%

This study shows that there could be variation of up to 2.4%

Warranty Information

Manufacturer's Warranty

i-SENS, Inc. warrants that the Soul Meter shall be free of defects in material and workmanship in normal use for a period of five (5) years. The meter must have been subjected to normal use. The warranty does not cover improper handling, tampering, use, or service of the meter. Any claim must be made within the warranty period.

i-SENS will, at its discretion, repair or replace a defective meter or meter part that is covered by this warranty.
As a matter of warranty policy, i-SENS will not reimburse the consumer's purchase price.

Obtaining Warranty Service
To obtain warranty service, you must return the defective meter or meter part along with proof of purchase to your nearest i-SENS Authorized Warranty Station.